REMARKS

Claims 5, 7, 9, 15, 24, 34, 37 and 38 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. This ground of rejection is traversed.

Claims 5, 7, 9, 15, 24, 37 and 38 have now been amended, without prejudice, to obviate this rejection, and claim 34 has been canceled. Claims 162-170 have now been added to capture those portions of the amended claims which have been deleted. Antecedent support for the newly added claims can be found in the original claims of he application.

Claims 1-27, 34, 35, 37-39, 41 and 43 stand rejected under 35 U.S.C. 103(a) as being obvious over Fuller et al. (USP 5,998,185) or WO 94/16058, in view of William et al. (USP 6,245,537 B1), Mikos et al. (USP 5,514,378) and Fuller (WO 97/08291). This ground of rejection is respectfully traversed.

The Fuller et al. ('185) primary reference discloses various structures made from silicone rubber which are useful as biological cell support structures. The '185 reference discloses various methods for increasing or decreasing the porosity or density of the structures. In particular, the reference states that in order to increase the density of the structures, stainless steel powder is incorporated during the manufacture of the material. See col. 2, line 62 to col. 3, line 1 of the reference. Conversely, when it is desired to increase the porosity of the structure, the liquid rubber precursor is aerated during its manufacture. See col. 3, lines 1-8. Accordingly, the '185 reference does not teach or suggest that a sacrificial filler material can be mixed with the silicone rubber precursor material prior to formation of the silicone rubber article as claimed in the present application.

The Fuller et al. (WO) primary reference relates to roller bottles used for promoting the growth of cells contained in biological fluids. The roller bottles can have an interior lining of silicone rubber, which acts as a growth surface for the cultured cells. The silicone rubber can be applied as a coating to the interior of the roller bottle, the salt particles can be contacted with the

surface of the silicone rubber, and the salt particles can be subsequently removed leaving a cratered or roughened interior surface.

The Examiner states that it would be obvious to modify the silicone rubber lining of the Fuller et al. (WO) reference to produce the three-dimensional silicone rubber article of the present invention. Applicants disagree with this conclusion. There is no disclosure in either of the Fuller et al. primary references to support the idea of mixing a biologically acceptable sacrificial filler material with a silicone rubber precursor material to form a self-supporting, three dimensional article having an interconnected network of pores or channels. See pages 5-7 of the present specification.

Both of the Fuller et al references fall short in several respects. First, the Fuller et. al. (WO) reference is directed to the preparation of coatings on the interior surfaces of roller bottles, rather than forming three dimensional articles. Second, the preparatory methods described in both references do not include a mixing step, as required in the present claims, whereby the filler is intimately mixed with the silicone rubber precursor. Rather, the sacrificial particles of the references are applied to the surface portion only of the silicone rubber. Consequently, following the teachings of the primary references, one skilled in the art would not be led to produce a three dimensional article having a multiplicity of interconnecting pores or channels.

The Williams et al. reference has been cited for its disclosure of the use of leaching in connection with the preparation of porous articles for tissue engineering. The disclosure in William et al. is limited to the use of leaching techniques to prepare porous membranes and tubes from polyhyroxyalkanoate (PHA). PHA was selected by Williams et al. since it has a low melting point and can be conveniently processed at relatively low temperatures. See col. 2, lines 44-66 of the reference. Moreover, PHA is biocompatible and degrades in the body into non-toxic metabolites. See col. 1 lines 39-61 of the reference. Thus, it can safely be used to prepare implantable medical devices.

In contrast to Williams et al., the silicone rubber polymer of the present invention is not physically or chemically degraded upon contact with body fluids, and is not pyrogenic. See page 1 of the present specification. Unlike the PHA material of Williams et al., which has a melting point below 136° C, the silicone rubber of the present invention is cured at elevated temperatures

which can easily exceed 136° C. There is no reason to surmise that a leaching technique that would be suitable for PHA polymers would also be appropriate for silicone rubber, and one skilled in the art would not look to art related to PHA polymers for guidance with respect to the processing of silicone rubber polymers.

The Mikos et al. reference is similar to Williams et al. in terms of its disclosure of the use of poly(alpha esters) for the manufacture of porous biodegradable membranes. Like Williams et al., Mikos et al. does not teach or suggest the use of silicone rubber polymers, and the reference does not recognize the difficulties inherent in the processing of such polymers. Accordingly, applicants submit that neither Williams et al. nor Mikos et al. can be properly combined with the primary references discussed above.

Claims 41 and 43 have been rejected under 35 U.S.C. 102(b) or 102(e) as being anticipated by Fuller et al. (WO 94/16058) or Fuller et al . ('185). This ground of rejection is also traversed.

Both of the Fuller et al. references are directed to the use of aeration for increasing the porosity of silicone rubber support structures. There is no evidence of record that the aeration technique of the references would produce a three dimensional structure having a network of interconnecting pores as does the process of the present invention. Applicants submit that aeration of the silicone rubber precursor leads to the formation of bubbles in the precursor material, and these bubbles remain in the material after curing and do not form an interconnecting network. Thus, for purposes of the present invention, the use of aeration to increase porosity results in a structure which is inferior to the structure of the present invention. In view of this circumstance, applicants point out that since the Fuller, et al. references do not disclose the use of a sacrificial material, there is no basis for presuming that the product prepared according to applicants' process would be equivalent to the product of the Fuller et al. references. See MPEP 2113.

Claims 1-27, 34, 35, 37-39, 41 and 43 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,998,185, in view of Williams et al., Mikos et al. and Fuller. This ground of rejection is traversed.

Applicants traverse this ground of rejection, essentially for reasons of record with respect to the traversal of the obviousness rejection as discussed above. The '185 patent discloses only the use of aeration to increase the porosity of silicone rubber articles, and there is no sound factual basis for combining this reference with the secondary references as asserted.

In view of the foregoing considerations, the claims of this application are now believed to overcome all remaining rejections, and to be in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections is solicited, and allowance of the remaining claims of this application is requested. The Examiner is invited to contact the undersigned if this would advance the prosecution of this application.

Respectfully submitted,

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